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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,620	02/08/2002	Gholam-Reza Zadno-Azizi	38349-0102C	3007

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

<b>Office Action Summary</b>	Application No. 10/071,620	Applicant(s) ZADNO-AZIZI ET AL.	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-52 is/are pending in the application.
- 4a) Of the above claim(s) 16-24,28-30 and 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27,31-33 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 24 April 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                               |                                                                             |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 4/24/03 has been entered as Paper No. 10. Changes to the drawings and specification have been approved by the Examiner. New claim 52 has been added.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 52 requires a frame be coupled to the valve body. This constitutes new matter because the specification does not support the frame being coupled (defined as "linked" or "connected") to the valve body. In fact, on page 6, lines 9-16, applicant teaches opposite of this claim limitation, specifically that a cylindrical element 36 between disk elements 38, 40 is used to separate the valve body from the seal, within which the frame is located. The specification teaches separating the valve body and the frame so that the valve body will not be distorted when the frame expands.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-27, 31-33 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (USPN 5,957,949 as cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in last office action).

Leonhardt et al. discloses a method of treating a patient using a flow control valve prosthesis with all the elements of claim 25, but is silent to placing the flow control device specifically in a pulmonic passageway of the patient. See column 1, lines 11-20 for placing in any passageway that flow control is desired a flow control device (20). See Figure 4 for the flow control device having a resilient seal (24) secured to (column 6, lines 25-26) a valve body (22). See Figures 9A-9D, column 5, lines 45-49 and column 11, lines 3-9 for expanding the resilient seal (24) to seal with a wall of the passageway so as to prevent fluid flow between the resilient seal and the wall of the passageway. Andersen et al. teaches that it is old and well known for a flow control valve prosthesis to be used in several different passageways, including the aorta and the pulmonary artery. See column 3, lines 43-52. It would have been obvious, therefore, to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to use the flow control device of Leonhardt et al., which is disclosed as being used in the aorta or any other passageway requiring flow control, in the alternative passageway of the pulmonary artery (pulmonic passageway).

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Claim 26, see Figure 4 for a frame (26) secured to (column 5, lines 61-62) the flow control device (20). See Figures 9A-9D for the flow control device being placed with the frame in an insertion state and the frame being expanded within the passageway to an expanded state.

Claim 27, see column 4, lines 26-28 for the frame (26) being comprised of a material having spring resilience. See Figures 9A-9D and columns 10-11, lines 53-21 for releasing the preconstraint (106) to allow the frame (26) to expand to an expanded state so as to engage the passageway.

Claim 31, see column 11, lines 3-9 and 20-22 for anchoring flow control device (20).

Claim 32, see column 11, lines 3-22 for resilient seal sealing against passageway during placement.

Claim 33, see column 1, lines 11-13 for one-way valve providing one direction fluid flow.

Claim 52, see column 6, lines 25-26 for a frame (26) coupled to the valve body (22).

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 25-27 and 31-33 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

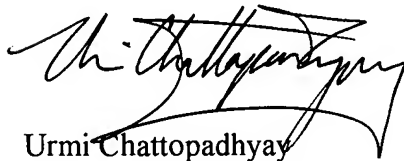
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

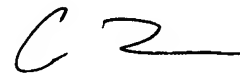
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



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July 9, 2003